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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,522	10/18/2001	Kendall M. Mohler	2982-A	8684

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EXAMINER	
ANDRES, JANET L	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,522	MOHLER, KENDALL M.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1,3-7 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,8-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 2, 8-10, and 12 in Paper No. 6 is acknowledged. The restriction requirement of paper no. 5 is made FINAL.

Specification

2. Applicant is reminded of the proper content of an abstract of the disclosure.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

The abstract is objected to because it does not contain a description of the invention to which the elected claims are directed, which is a method of treating rheumatoid arthritis with an anti-IL-17 receptor antibody.

3. The use of the trademark ENBREL has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent 6,072,037 (Yao et al., 2000) in view of Chabaud et al., Arthritis and Rheumatism, 1999, vol. 42, no. 5, pp. 963-970.

The applied patent has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is drawn to methods using anti-IL-17 receptor antibodies to treat rheumatoid arthritis. The '037 patent teaches antibodies to the IL-17 receptor in column in column 14, lines 66-67, and column 15, lines 1-44 and teaches that it can be used to interfere with binding of IL-17 (referred to as CTLA8) to the IL-17 receptor (column 15, lines 4-8). The '037 patent fails to teach the use of anti-IL-17 receptor antibodies to treat rheumatoid arthritis. Chabaud et al. teaches that IL-17 is present in rheumatoid arthritis and that it causes the secretion of pro-inflammatory cytokines (p. 965, figure 1 and text, p. 966, table 1). Chaubaud et al. further teaches that this pro-inflammatory effect can be inhibited using an anti-IL-17 antibody (p. 965, figure 1 and column 2, p. 968, table 2). Chabaud et al. concludes that IL-17, along with IL-1 and TNF-α, represents a target for treatment of rheumatoid arthritis. Chabaud et al. fails to teach the use of anti-IL-17 receptor antibodies to treat rheumatoid arthritis. However, it would be *prima facie* obvious to one of ordinary skill in the art to combine the teachings of the '037 patent with those of Chabaud et al. to use anti-IL-17 receptor antibodies to treat rheumatoid arthritis. One of ordinary skill would be motivated to do so because Chabaud et al. teaches that inhibition of IL-17 action using an anti-IL-17 antibody is useful to prevent the induction of pro-inflammatory cytokines in rheumatoid arthritis, and the '037 patent teaches that anti-IL-17

receptor antibodies can also be used to prevent IL-17 action. Thus one of ordinary skill would expect such anti-receptor antibodies to have effects similar to those taught be Chabaud et al. and would thus also expect them to be useful in the treatment of rheumatoid arthritis.

6. Claims 8-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent the '037 patent in view of Chabaud et al. as applied to claim 2 above, and further in view of Arend et al., Arthritis and Rheumatism, vol. 38, no. 2, 1995, pp. 151-160.

The '037 patent and Chabaud et al. teach as set forth above but fail to teach the administration of TNF antagonists, IL-1 antagonists, or disease-modifying antirheumatic drugs (DMARDs) such as methotrexate to treat rheumatoid arthritis. Arend et al. teaches that antibodies to IL-1 as well as the competitive inhibitor IL-1ra can be used to block the effects of joint destruction in rheumatoid arthritis tissue (p. 153, column 1). Arend et al. further teaches that methotrexate can be used to treat rheumatoid arthritis (p. 154, column 2, p. 157, column 1). Soluble anti-IL-1 type I and type II receptors for this purpose are taught on p. 155, column 1 and p. 157, column 2. That beneficial effects have been observed in clinical trials using monoclonal antibodies to TNF-α and soluble p75 and p55 TNF-α receptors to treat rheumatoid arthritis is taught on p. 157, columns 1 and 2. Arend et al. additionally teaches that such agents should be used together or in combination with more traditional treatments on p. 157, column 2. Arend et al. fails to teach the use of anti-IL-17 receptor antibodies in combination with these agents. However, it would be *prima facie* obvious to one of ordinary skill in the art to combine the teachings of the '037 patent and Chabaud et al. with those of Arend et al. to use such combinations. One of ordinary skill would be motivated to do so because the agents individually

would be useful to treat the rheumatoid arthritis, and thus one of ordinary skill would expect success from such a combination. *In re Kerkhoven* (205 USPQ 1069, CCPA 1980) summarizes:

> "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a combination that is to be used for the very same purpose: the idea of combining them flows logically from their having been individually taught in the prior art."

Further, Arend et al. explicitly teaches that a combination of agents should be used on p. 157, column 2.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly

set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
Patent Examiner

March 23, 2003